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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/430,966 11/01/99 DE CORTE

B JAB-1425

EXAMINER

HM22/1124

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ART UNIT

PAPER NUMBER

1624

DATE MAILED:

11/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/430,966

Applicant(s)

De Corte et al.

Examiner
Venkataraman Balasubramanian

Group Art Unit
1624



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-14, 16, and 17 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 8-14 and 16-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Applicants' preliminary amendment which involved cancellation of claims 7 and 15 and amendment to claims 3-6, 8-14 and 16-17, filed on 11/01/1999 is made of record.

Claims 1-6, 8-14 and 16-17 are now pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-14 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of "addition salt" in claim 1 is indefinite as it is not clear what is the structural make-up of the product of the "addition" process.
2. Claim 1 is also indefinite as it recites " quaternary amine". It is not clear what "quaternary amine" is being referred to and where the group is to be present.
3. Also in claim 1 in the definition of various R groups, the presence of a parenthesis in the group "di(methyl)aminocarbonyl is unclear.
4. Reason # 1 and 2 also apply to claim 6.

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5. Recitation of R⁴ and R⁵ taken together may form a "azido", in claim 1 and 8, is indefinite as it is not clear how such a group could be formed.
6. Claim 14 is a substantially duplicate of claim 16 as they both depend on the same scope of active ingredient and have no material difference. Different intended uses in such claims are given no significant weight. Note In re Tuominen 213 USPQ 89.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-14 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Representative examples of structurally diverse compounds generically embraced as seen in the definition of L, Q, Y and various R groups in the invention are not shown to possess in vitro activity much less in vivo use claimed herein. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same bioactivity profile since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding

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sufficiency of disclosure for Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive art such as the pharmaceuticals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchings et al. US 6,048,86.

Hutchings et al. teach several substituted 2-anilinopyrimidines which includes compounds generically embraced herein for the treatment of immune diseases and hyperproliferative disorders. See formula I on col. 1 and note the definitions of R¹, R², R³, R⁴, R⁵, R⁶ and R⁷ groups. Particularly note R⁵ definition includes Q group embraced herein and R⁶ definition includes Y groups embraced herein and S-R⁷ corresponds to L group of the instant claims. Also note the anilino group corresponds to partial structure b-1 of instant claims and R¹, R² and R³ embrace groups recited herein for R² and R^{2a}. See col. 2-10 for various preferred embodiments and pharmaceutical compositions. See col. 12-15 for the process for making these compounds and Examples 1-31 for compounds made shown on col. 16-25.

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Instant claims differs from the reference in requiring R^{2a} to be in the para position of the aminophenyl ring . However Hutchings et al. teaches both the equivalency and interchangeability of herein exemplified substituents with that claimed herein. See cols. 1-10 , formula I, especially the definitions of the definitions of R^1 , R^2 , R^3 , R^4 , R^5 , R^6 and R^7 groups as noted above. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in pyrimidine ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 6,093,716.

Davis et al. teach several substituted 2-heteroaminopyrimidines whcih includes compounds generically embraced herein for the treatment of immune diseases and hyperproliferative disorders. See formula I on col. 1 and note the definitions of R^1 , R^2 , R^3 and Het groups. Particularly note Q is hydrogen, the instant claims read on Davis et al. More specifically, note R^2 definition includes Y groups embraced herein and R^3 corresponds to L group of the instant claims. Also note the Het group corresponds to partial structure b-2 through b-7 of instant claims and optional substituents of Het groups embrace groups recited herein for R^2 and R^{2a} . See col. 2-7 for variuos preferred embodiments and pharmaceutical compositions. See col. 9-12 for the process for making these compounds and Examples 1-20 for compounds made shown on col. 12-20.

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Instant claims differs from the reference in requiring R^{2a} to be in the para position of the aminophenyl ring . However Davis et al. teaches both the equivalency and interchangeability of herein exemplified substituents with that claimed herein. See cols. 1-2 , formula I, especially the definitions of the definitions of optional substituents for Het (col. 2 lines 35-55) and R^1 , R^2 and R^3 , groups as noted above. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in pyrimidine ring and the Het ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

The instant claims also differ from the reference in Q being an methyl group(ie C_1 alkyl).

While said compound doesn't anticipate the scope of the instant claims, they are very closely related, having a hydrogen on the ring 6-position of pyrimidine ring vs methyl group in the instant. However, compounds that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me on nitrogen, see Ex parte Weston 121 USPQ 428; In re Doebel 174 USPQ 156. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman et al. US 5,691,364.

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Buckman et al. teach several 2,4-disubstituted pyrimidines which includes compounds generically embraced herein for the treatment of thrombosis and related disorders. See formula III, V and VIII on col. 3-4 and note the definitions of R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , Z^1 and Z^2 groups. Particularly note when Z^1 and Z^2 are hetero atoms, and Y is R^2 of reference, the instant claims read on Buckman et al. More specifically, note R^2 and R^3 definition includes Y groups and Q groups embraced herein and R^4 , R^5 , R^6 and R^7 corresponds to groups recited herein for R^2 and R^{2a} . See col. 4-10 for various preferred embodiments and pharmaceutical compositions. See col. 22-31 for the process for making these compounds and Examples 1-14 for compounds made shown on col. 32-800.

Instant claims differs from the reference in requiring R^{2a} to be in the para position of the aminophenyl ring. However Buckman et al. teaches both the equivalency and interchangeability of herein exemplified substituents with that claimed herein. See cols. 4, formula III, V and VIII, especially the definitions of R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , Z^1 and Z^2 groups as noted above. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in pyrimidine ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Reference cited in the Information Disclosure Statement is made of record.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on weekdays from 8.30 AM to 5.00 PM.

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The fax phone number for the organization where this application or proceeding is assigned
(703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding
should be directed to the receptionist whose telephone number is (703) 308-1235.

VB

V. Balasubramanian (Bala)

11/20/2000

Mukund J. Shah

MUKUND J. SHAH

SUPERVISORY PATENT EXAMINER

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